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| APPLICATION I | ٧٥.                 | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |  |
|---------------|---------------------|-------------|----------------------|-----------------------|------------------|--|
| 10/608,937    |                     | 06/27/2003  | Andrea Piva          | 35826                 | 6954             |  |
| 116           | 7590                | 03/10/2006  |                      | EXAMINER              |                  |  |
|               | PEARNE & GORDON LLP |             |                      |                       | SHAH, CHIRAG V   |  |
| SUITE 1       | ST 9TH STI<br>200   | (EEI        |                      | ART UNIT PAPER NUMBER |                  |  |
| CLEVEI        | AND, OH             | 44114-3108  | 1761                 |                       |                  |  |

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |   | Application No.   | Applicant(s)   |
|--|---|---|--|
|  |   | 10/608,937  | PIVA ET AL.  |
| Offi   | ice Action Summary  | Examiner  | Art Unit   |
|  |   | Chirag V. Shah  | 1761   |
| The M<br>Period for Reply  | AILING DATE of this communication app   | ears on the cover sheet with the c  | orrespondence address  |
| WHICHEVER - Extensions of tin after SIX (6) MO - If NO period for - Failure to reply v Any reply receiv  | ED STATUTORY PERIOD FOR REPLY IS LONGER, FROM THE MAILING DATE of the available under the provisions of 37 CFR 1.13 INTHS from the mailing date of this communication. The reply is specified above, the maximum statutory period within the set or extended period for reply will, by statute, and by the Office later than three months after the mailing term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |
| Status   |   |   |  |
| 1)☐ Respor   | nsive to communication(s) filed on <u>27 <i>Ju</i></u>  | <u>ine 2003</u> .   |  |
| 2a)∐ This ac   | tion is <b>FINAL</b> . 2b)⊠ This  | action is non-final.  |  |
| ·—   | his application is in condition for allowan   | •   |  |
| closed   | in accordance with the practice under E   | x parte Quayle, 1935 C.D. 11, 48  | 53 O.G. 213.   |
| Disposition of C   | laims   |   |  |
| 4a) Of the first | s) 1-20 is/are pending in the application.  the above claim(s) is/are withdraw  s) is/are allowed.  s) is/are rejected.  s) is/are objected to.  s) are subject to restriction and/or   | vn from consideration.  |  |
| Application Pap  | ers   |   |  |
| 10)⊠ The dra<br>Applicar<br>Replace  | ecification is objected to by the Examiner wing(s) filed on 27 June 2003 is/are: a) int may not request that any objection to the dement drawing sheet(s) including the correction or declaration is objected to by the Example 2015.   | accepted or b) objected to drawing(s) be held in abeyance. Section is required if the drawing(s) is object.   | e 37 CFR 1.85(a).<br>jected to. See 37 CFR 1.121(d).                       |
| Priority under 35  | 5 U.S.C. § 119  |   |  |
| 12)  | eledgment is made of a claim for foreign b) Some * c) None of:  Certified copies of the priority documents Certified copies of the priority documents Copies of the certified copies of the prior application from the International Bureau attached detailed Office action for a list of   | s have been received.<br>s have been received in Applicati<br>ity documents have been receive<br>ı (PCT Rule 17.2(a)).  | on No ed in this National Stage  |
| 2) Notice of Drafts 3) Information Dis   | rences Cited (PTO-892)<br>sperson's Patent Drawing Review (PTO-948)<br>sclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>ail Date  | 4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:   | (PTO-413)<br>ate<br>Patent Application (PTO-152)                           |

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**DETAILED ACTION** 

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Claim Objections

1. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for

failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the

claim(s) in independent form. The claim recites "... according to claim 1...lipid matrix consists

of animal triglyceride chosen among bovine tallow or swine lard" adds a broader requirement. It

is recommended to place this limitation in independent claim 1.

2. Claim 16 is objected to because of the following informalities: Please replace "feeded"

with feed. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claims 1, 2, 3, 5, 7, 8, 9, 10,12,14 are rejected under 35 U.S.C. 102(b) as being anticipated by Morgan et al (US 5204029).

Morgan et al teaches a microencapsulated composition for food application (abstract, col. 1, lines 3-15) comprising hydrogenated vegetal oils such as: sunflower oil, corn oil, soybean oil, palm oil, corn oil and others. (col. 3, lines 35-60); organic and organic salts such as: citric acid and potassium sorbate (col.5, lines 15-45); and use of flavoring agents (col. 4, lines 42-50 and col.5, lines 15-45) and essential oils (col. 4, lines 42-50).

Morgan et al address the limitations of claims 2, 3, 5, 8-10, 12 and 14. Morgan teaches use of both bovine tallow and swine lard (col. 3, lines 35-45); also, Morgan discloses microencapsulate diameter in the range of 180 – 1000 microns, thus meeting the limitation of instant claim 5 and 14. Furthermore. Morgan has disclosed use of citric acid and potassium sorbate (col. 5,lines 38-45) meeting the limitations of the specific examples disclosed by applicant.

Morgan meets the method of claim 7. Morgan teaches a method of making a composition by placing the homogenous composition of a melted lipid matrix and additives, including an organic salt/acid and essential oils (see col. 3-5 for the composition mixture of the "core material") in a container and later spray cooled in an enclosed environment. ( see fig. 1, col. 2, lines 32-60).

In light of the above, it is clear that Morgan et al anticipates the presently cited claims.

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## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 5. Claims 1-5, 7-14, 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al (US 5204029) in view of Porzio et al. (US 5897897).

Morgan et al teaches a microencapsulated composition for food application (abstract, col. 1, lines 3-15) comprising hydrogenated vegetal oils such as: sunflower oil, corn oil, soybean oil, palm oil, corn oil and others. (col. 3, lines 35-60); organic and organic salts such as: citric acid and potassium sorbate (col.5, lines 15-45); and use of flavoring agents (col. 4, lines 42-50 and col.5, lines 15-45) and essential oils (col. 4, lines 42-50).

Although Morgan discloses that the "core material" which includes the organic acid and organic salts are found in the range of 1% - 35% by weight, (col. 4, lines 50-60) specific

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disclosure of individual ingredients is not made. Moreover, Morgan is silent as to the use of oleoresins, as described in claim 1.

Porzio et al. also in the same field of endeavor of making encapsulation compositions teaches use if organic salts and acids such as: citric acid, fumaric acid and malic acid (col. 9, lines 30-40) in the range of 1-15% (col.4, ln 15-25). In addition, Porzio disclose the use of oleoresins, herbs, essential oils and other natural aromatizing agents (col. 6, lines 35-60). Given that Porzio et al, in the same field of endeavor as Morgan, it would have been obvious to combine the disclosure of Morgan and add organic salts and oleoresin compounds in the range disclosed by Porzio to arrive at the composition in claim 1 for one skilled in the art and generate the claimed invention with a reasonable expectation of success.

- 4. Morgan et al address claims 2-5. Morgan teaches use of both bovine tallow and swine lard (col. 3, lines 35-45); also, Morgan discloses microencapsulate diameter in the range of 180 1000 microns, thus meeting the limitation of instant claim 5. Furthermore. Morgan has disclosed use of potassium sorbate (col. 5,lines 38-45) and Morgan has generally stated that "core" material is found in the range of 1-35% (col. 4, lines 50-60). Specific disclosure to the amount of potassium sorbate or other organic salts is not made. However, adding organic salts or organic acids in the limitation of claim 4 would have been obvious to one of ordinary skill to achieve the desired results.
- 5. Claim 7 further requires a method step for preparing the claimed composition. Morgan meets the method of claim 7. Morgan teaches a method of making a composition by placing the

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homogenous composition of a melted lipid matrix and additives, including an organic salt/acid and essential oils (see col. 3-5 for the composition mixture of the "core material") in a container and later spray cooled in an enclosed environment. (see fig. 1, col. 2, lines 32-60). Morgan does not specifically state "homogenous mass" or "cold room" as stated in claim 7. However, Morgan states "the core is the discontinuous or inner phase" and is emulsified and the temperature exceeds the melting point (col. 2, lines 40-60). In addition, the homogenous mixture is later "spray cooled" in the container. Thus, it would be obvious to one of ordinary skill to interpreter "the core is the discontinuous or inner phase" as a homogenous mixture. Furthermore, spray cooling in a room or spray cooling the mixture in the container would like achieve the same result and thus no distinguishable patentable difference is seen at this time.

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6. Claim 16 requires that the disclosed composition is fed to monogastric animals to contrast the development of bacteria or pathogenic fungi in the gastro resistant system. It is the examiner's position that the composition of Morgan, which contains the same active ingredients as claimed in the applicant's composition would possess the same beneficial biological and physiological properties. Moreover, feeding this composition would be obvious to one of ordinary skill. The ruminant by pass problems are well known and a composition that can deliver necessary nutrients without degradation is of great demand and thus one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success.

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7. Claim 20 requires the equilibration in the intestinal microbism. As the composition has

been disclosed above, it is seen that the intestinal microbism would have been equilibrated by

feed in the claimed composition. Therefore it would have been obvious to use a known

composition in the method of claim 16to reach equilibration in the intestinal microbism.

8. Claims 8-14, 17-19 are addressed in paragraphs 3-5 above and thus are obvious for the

stated reasons.

9. Claims 6 and 15 rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al

(US 5204029) in view of Porzio et al. (US 5897897), as applied to the above claims, and further

in view of Ribier et al (US 5747518),

Morgan is silent as to the inclusion of orthophosphoric acid. Ribier et al in disclosing an

invention to encapsulate a lipid matrix. Site of discloses use of this compound in the range of

15% (col. 13, lines 22-26). Thus it would have been obvious for one of ordinary skill to combine

the disclosure made by Morgan and Porzio and add the beneficial of this mineral acid disclosed

by Ribier and generate the claimed invention with a reasonable expectation of success.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chirag V. Shah whose telephone number is 571-272-2766. The examiner can normally be reached on Mon-Thurs 7:30am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

> Chirag V. Shah Patent Examiner AU 1761

03/06/06